Attachment A
Comments on
Proposed Amendments to the Hospital Licensure Regulations (105 CMR 130.000)
Regarding Primary Stroke Services

Name and Affiliation	Comment	Response
Public Hearing Comments:		
David Day American Stroke Association	Support the proposed regulations	
Lee Schwamm, M.D. Partners Healthcare System, MGH Acute Stroke Service, Physician volunteer representative for American Heart Association and American Stroke Association	Support the proposed regulations; Recommended that the hospitals need to document the date and time of symptom onset for all stroke patients to determine which patients arrived within three hours of symptom onset.	Date and time of symptom onset will be included in the data set.
Bruce Auerbach, M.D. Sturdy Memorial Hospital, Emergency and Ambulatory Surgery	Support the proposed regulations; Recommended that the Department should be reasonable and cautious regarding the implementation of the timelines and allow institutions latitude due to travel time to nearest facility.	The Department's goal is to work with all hospitals that wish to be designated so they will receive designation.
Gert Walter, M.D. Emerson Hospital	Support the proposed regulations; Recommended that the Department add a requirement for public education regarding stroke.	105 CMR 130.1412 Community Education has been added to the regulations. As noted in Dr. Walter's comments, according to the August 2003 DPH stroke survey of hospitals, of the seventy-three hospitals responding, 49% of hospitals already provide public education regarding stroke. Upon request, the Department will provide technical assistance to hospitals developing a public education program.
Additional Written Comments:		
Lisa DeMello, RN QI & Outcomes Manager Saint Anne's Hospital Data coordinator and hospital liaison for the American Stroke Association Get with the Guidelines Pilot Program	Support the proposed regulations. Does not find the collection of time and outcome data (symptom onset, patient arrival at ED, completion of CT or MRI scan, initiation of thrombolytic therapy, or if not administered, reason(s) for non-treatment, and in-hospital mortality and discharge destination) for patients arriving at less than three hours after symptom	The Department will limit its data set to the minimum possible data elements but sufficient for hospitals and the Department to assess attainment and/or improvement in the overall goal of provision of FDA approved thrombolytic therapy to acute ischemic stroke patients within three hours of symptom onset.

	onset as overly burdensome for hospitals. Estimates data entry into the online tool at less than 5 minutes per chart. The time it takes to collect the data varies and could be streamlined with a single form for each acute stroke patient.	
Barry McKay Gloucester Fire Chief	Provided a copy of comments previously submitted regarding Proposed Amendments to the EMS Regulations that would require EMS services compliance with regional point-of-entry trauma plans. His concerns relate to the geographic constraints of Gloucester and difficulty with transport when roads providing local egress are blocked. Asks if point-of-entry planning is envisioned for acute stroke patients and if so, how will the EMS community have the opportunity to review and comment on these plans. Recommends that the Department review all point-of-entry plans, upon request hold a public hearing to allow community input and revise point-of-entry plans, as appropriate, based on the public comment prior to approval of the plan.	(Those comments relevant to the trauma regulations will be addressed in a separate document) The Department does envision the development of point-of-entry planning for acute stroke services. Point-of-entry plans are regulated by the Office of Emergency Medical Services (OEMS) and these comments have been forwarded to that office.
Anuj Goel, Esq. Director, Regulatory Compliance Mass. Hospital Association	Recommends several changes to relieve possible administrative burdens on hospitals: 1) Eliminate the term 'data center' as MHA sees it as a costly and duplicative reporting requirement. Recommends using existing data reporting requirements hospitals currently maintain, e.g., Division of Health Care Finance and Policy (DHCFP) reported data. Recommends alternative language in section 130.1410: The hospital shall submit data in a manner defined by the Department and in accordance with the protocols established by the Department in an advisory bulletin.	The Department eliminated the term 'data center' from the regulations and will address the data set and reporting requirements in the advisory bulletin, which will give the Department greater flexibility if the prescribed data or method of data collection need to be modified. The Department incorporated the recommended language for 105 CMR 130.1410. The data available through DHCFP does not contain the data elements required to assess the effectiveness of a Primary Stroke Service. That system is not designed to perform the QA

		function contemplated in these regulations.
	2) 'Provision' vs. 'Designation'. MHA's concern is that, as written, the regulations appear to allow only designated services to treat stroke patients who may arrive at the hospital by other than ambulance transport. MHA offered the following alternative language: • Amend 130.1400 to state "The purpose of 105 CMR 130.1400 through 105 CMR 130.1412 is to establish standards for the delivery of Primary Stroke Services in a hospital with licensed Emergency Services" • Amend 130.1402 to state "each hospital seeking to provide Primary Stroke Services shall submit to the Department, in a manner prescribed by the Department, their specific protocols documenting how the hospital will meet the standards in 105 CMR 130.1400 through 105 CMR 130.1412." • Amend the first line of 130.1403 to state "the hospital shall provide Primary Stroke Service upon demonstration…"	The Department has not incorporated these changes. As written, the regulations do not prohibit non-designated services from treating stroke patients. This issue will be further clarified in the OEMS point-of-entry plans.
	3) Because the Department is planning to release guidance outlining applicable time periods, delete the terms 'rapid' and 'rapidly' throughout the regulations, except in 130.1401 (definition of Acute Stroke).	Time sensitivity is an important part of these regulations. The Department has replaced the words 'rapid' and 'rapidly' with 'prompt' or 'promptly', except in the definitions of Acute Hemorrhagic Stroke, Acute Ischemic Stroke and Acute Stroke. The regulations further state that the prompt actions need to be consistent with time targets acceptable to the Department. The Department added a sentence in 105 CMR 130.1405 to clarify that time to treatment under the hospital's written care protocols must be

		consistent with time targets acceptable to the Department.
	4) Amend 130.1412 to reflect that the governing body of the hospital only conducts the review of the stroke service protocols.	As written, the regulation does not preclude the governing body from conducting the review.
	5) Delay implementation of the regulations until an advisory group representing the various provider groups and hospitals has met to develop the advisory bulletins because hospitals need to know what will be required prior to meeting the applicable stroke criteria and to ensure that the criteria meet the local standards of practice.	The Department is working with MHA to develop the advisory bulletin and estimates that the bulletin will be issued in March. The Department does not need to delay promulgation of the regulations because designation is completely elective. Hospitals will be able to apply for designation after the Department develops application forms and issues the advisory bulletin; promulgation of these amendments puts the framework in place.
Anne Young, M.D. Chief, Neurology Service, MGH	Support the proposed regulations	
Peter Moyer, M.D. Medical Director, Boston EMS, Boston Fire and Boston Police	Support the proposed regulations	
Suzanne Wedel, M.D. Chief Executive Officer Boston MedFlight	Support the proposed regulations	
Alasdair Conn, M.D. Chief of Emergency Services MGH	Support the proposed regulations	
Gray Ellrodt, M.D. Chair, Department of Medicine Berkshire Medical Center	Support the proposed regulations	
David Hiltz, NREMT-P Regional Manager, Emergency Cardiovascular Care Programs of the American Heart Association	Support the proposed regulations	